



UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 25 2009

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,204,257. The application was filed on February 6, 2009, under 35 U.S.C. § 156. Please note that Applicant has also applied for extension for U.S. Patent No. 6,872,838 for NDA No. 22-244 pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Tiff
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Christopher N. Sipes
Covington & Burling LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004-2401

RE: LUSEDRA™ (fospropofol disodium)
Docket No. FDA-2009-E-0204